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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/840,090 | 05/06/2004 | Keith T. Carron | UW-2 | 7838 |
| 28581 | 7590 | 11/14/2007 | | |
| DUANE MORRIS LLP PO BOX 5203 PRINCETON, NJ 08543-5203 | | | EXAMINER MUI, CHRISTINE T | |
| | | | ART UNIT 1797 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/840,090 | Applicant(s) CARRON ET AL. | |
| | Examiner Christine T. Mui | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 18-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 May 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :16 February 2005; 23 October 2007.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-17 in the reply filed on 22 October 2007 is acknowledged.

1. Claims 18-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 22 October 2007.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show embodiment 120 in Figure 8 as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after

the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to because in Figure 8, character "12" probably should read "120" as described in the specification on page 19 [0072]. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

1. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
2. It is unclear to the examiner what is meant by a nanoparticle-like texture. Any coating on a surface as some sort of texture associated with it.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-12 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/59234 to Carron et al. (herein referred to as "Carron").
3. Regarding claim 1, the reference Carron discloses a method for the detection of a controlled substance where a sensor is coated with molecules on a spectroscopic surface. In the method, a sample surface or sample is provided to the analyzer and some type of source provides one or more wavelengths of energy to which a spectroscopic sample is exposed. In the situation of Surface Enhanced Raman Scattering, the spectroscopic sample surface may have characteristics so that the

spectroscopic sample surface can interact and provide an appropriate Raman scattering or surface enhanced Raman scattering. Once the interaction has occurred a detector determines an analysis of the spectroscopic surface. The analysis may consist of a computer determination through comparison software or some other determination to gain information with respect to the analyte or controlled substance. The coating on the sensor may consist of a variety of chemical classes such as those having carbon atoms in their structure and even non-protein group. In a preferred embodiment, a diazonium compound or some derivative of that compound could be used as a sensor coating (see page 13, lines 22-30, page 14, lines 9-13, page 15, lines 13-17, page 17, line 28 – page 18, line 2).

4. Regarding claim 2, the reference Carron discloses the sample can either have on it, or be itself, some type of sensor molecule which interacts with the analyte of interest or the spectroscopic sample surface may actually be a Raman spectroscopic sample surface or a Raman surface, a type of surface which provides the appropriate interactions to achieve the Raman scattering phenomenon (see page 15, lines 7-8, 19-24). It is interpreted by the examiner that the sample and the spectroscopic sample surface that provides the appropriate interaction to achieve the Raman scattering phenomenon is one that enhances Raman scattering.

5. Regarding claim 3, the reference Carron discloses utilizing permanent or covalent bonding of the analyte or controlled substance to the spectroscopic sample surface the may be washed away with a liquid to remove excess analyte or to stop the continued creation of the bonding of the analyte. With respect to stopping the creation

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of additional bonding, a greater degree of accuracy is possible in that the sample surface prior to being presented to the analyzer, may be washed at a specific time to completely stop any continued creation of the covalent bond (see page 20, lines 9-10).

6. Regarding claim 4, the reference Carron discloses the sample can have on it some type of sensor molecule which interacts with the analyte to alter the results of the spectroscopic signal that changes the emission or adsorption wavelength of energy to produce a signature which can be analyzed and determined uniquely as a result of the particular analyte desired (see page 15, lines 4-8). It is interpreted by the examiner that the sample with some type of sensor molecule that interacts with the analyte of interest or controlled substance can act as an intermediate uniquely determining the analyte of interest.

7. Regarding claim 5, the reference Carron discloses the spectroscopic surface as one that provides the appropriate interactions to achieve the Surface Enhanced Raman Scattering phenomenon by being an actual Raman spectroscopic surface or a Raman surface. The sample on the spectroscopic surface may have some type of sensor molecule that interacts with the analyte (see page 15, lines 4-8, 19-26). It is interpreted by the examiner that the sensor molecule on the sample, which is on the spectroscopic surface, is an activator that promotes SERS of the analyte of interest.

8. Regarding claim 6, the reference Carron discloses that analyte or controlled substance that is covalently bonded to the sample surface may be washed with a liquid to remove excess analyte to stop the continued reaction of the bonding of the analyte over a period of time or to remove interfering substance. By removing any interfering

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substances, the stops the creation of the covalent bonding of the analyte to the coating or the stop of removing interfering substances (see page 20, lines 2-15). It is interpreted by the examiner that by washing the surface removing any interfering substance, stabilizes the surface for Raman scattering.

9. Regarding claim 7, the reference Carron discloses modifier can be attached to some aspect of the coating to achieve a desired result. The modifier may serve to reserve a position on the molecule to react with the controlled substance or analyte, or may serve to influence the reactivity between the reactive functional group and the analyte or might serve to tune or influence the reaction to a desired degree. The tuning may serve to provide different ranges or concentrations at which the analyte coating would react. The coating a dissolveable overcoating. (see page 30, lines 9-16, page 23, lines 21-23). It is interpreted by the examiner that where the modifier attached to the coating where it influences the reactivity between the reactive functional group and the analyte may serve as a sacrificial agent being dissolved.

10. Regarding claim 8, the reference Carron discloses the sensor coating can be exposed to the analyte. The analyte may be contained within a solid, liquid or gas under conditions, which might allow a chemical reaction to take place between the sensor molecules and the analyte (see page 21, lines 11-13).

11. Regarding claim 9, the reference Carron discloses in coating the sensor, the sensor coating stability can be solved by appropriate measures such as a dissolveable overcoating on the surface or the use of otherwise hermetically sealed surfaces (see page 23, lines 21-23).

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12. Regarding claims 10-12, the reference Carron discloses the surface of the attachment group is designed to hold the coating of the surface so the choice of the SAG depends on the surface involved. Carron discloses that one possible surface can be metal surfaces. Likely metal surfaces include silver, gold, copper and mercury, which are particularly appropriate SAG for the surfaces appear to be the thiol group RSH or some derivative of the thiol group (see page 21, lines 23- page, 22, line 3).

13. Regarding claim 17, the reference Carron discloses the a modifier can be attached to some aspect of the coating to achieve a desired result to serve to reserve a position on the molecule to react with the controlled substance or analyte involved. Cyanide may be used in a reversible fashion that forms an adduct which results from the covalent bonding on the surface of the spectroscopic surface that aids in the detection of an analyte or a controlled substance (se page 31, lines 12-30).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carron as applied to claim 1 above, and further in view of Sulk et al. (submitted on the Information Disclosure Statement on 23 October 2007, herein referred "Sulk").

18. Regarding claims 13-16, the reference Carron discloses the claimed invention except for where the surface is of a nanoparticle of a colloidal form and a solution. Sulk discloses a study to detect bilirubin and salicylate in whole blood (lyophilized) using SERS and a reactive coating. This study was conducted to develop an assay that would simplify an analysis by detection the analyte in a whole blood sample. In the coating provided, a reactive diazonium group, an electron-deficient aromatic ring and a tethering agent for the attachment to silver colloids. The silver colloid suspensions (nanoparticle colloidal solution, nanoparticle-like texture) are prepared by the addition of water for every 50 mg of colloid precipitate be for a SERS spectrum (see abstract, page

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853, left column, page 854, right column). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the surface of a sample be of a nanoparticle colloidal suspension so that upon capturing of an analyte in the coating the small sized sample surface can eliminate the interference from contaminants, reagent or other components and increase the signal of all components of a sample during Raman amplification.

19. Claims 13-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carron as applied to claim 1 above, and further in view of US Publication No. 2004/0135997 A1 to Chan et al (herein referred "Chan").

20. Regarding claims 13-14 and 16, the reference Carron discloses the claimed invention except for where the surface is of a nanoparticle of a colloidal form and a solution. Chan discloses an apparatus that using metal-coated nanocrystalline porous silicon substrates that may be metal coated, nanocrystalline, or immobilized meal colloids. A thin coating of Raman active metal such as gold or silver is coated onto the porous substrate. The Raman spectroscopy is used to detect nucleotides, purines or pyrimidines at the single molecule level (see abstract, [0042]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the surface that is exposed to Raman spectroscopy be made up of nanoparticles to enhance the Raman signal during detection and identification and quantification of analytes.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine T. Mui whose telephone number is (571) 270-3243. The examiner can normally be reached on Monday-Friday 8-5; Alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM


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SUPERVISORY PATENT EXAMINER